

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

YOSHITAKE et al.

Serial No. 10/594,436

Filed: September 26, 2006

Confirmation No. 2325

Atty. Ref.: 1050-4

T.C. / Art Unit: 1611

Examiner: K.S. Orwig

FOR: CONTROLLED-RELEASE PHARMACEUTICAL COMPOSITION AND METHOD
FOR PRODUCING THE SAME

* * *

SUPPLEMENTAL RESPONSE

June 7, 2010

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the response filed May 5, 2010, consideration of the attached Rule 132 Declaration is respectfully requested. This evidence is supported in support of the arguments of record. It demonstrates the patentability of the pending claims because of the criticality of the range from 20 to 35 wt% of a hydrophobic wax to the pulsatile dissolution property of the composition. Where the ratio is lower than this range, the dispersed components aggregated in the coating suspension, whereby the variation in the dissolution lag time increased. Moreover, where the ratio was higher than this range, the strength of the release-controlling coating decreased, whereby the acid resistance could not be ensured and a suitable dissolution lag time could not be obtained.

Please contact the undersigned if additional information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Gary R. Tanigawa/
Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100